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Patents and publications

1 6,942,696 Ossicular prosthesis adjusting device
2 6,726,719 Attachment mechanism for middle ear prosthesis
3 6,585,864 Coating system for high temperature stainless steel
4 6,168,62 Adjustable length prosthesis useful for ossicular replacement and reconstruction
5 5,728,157 Biocompatible composite prostheses
6 5,578,086 Prosthesis using biocompatible composite material
7 5,554,188 Universal middle ear prosthesis
8 5,522,896 Biocompatible composite material
9 5,220,918 Trans-tympanic connector for magnetic induction hearing aid
10 5,061,280 Ossicular prosthesis
11 4,840,178 Magnet for installation in the middle ear
12 4,800,884 Magnetic induction hearing aid
13 4,568,337 Ventilation tube permitting two-way gaseous communication with one-way liquid valve

Professional memberships

Society for Biomaterials

Attachment A

Middle Ear, Ossiculoplasty

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AUTHOR INFORMATION

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Disclosure

INTRODUCTION

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History of the Procedure: The earliest recorded attempt to reestablish a connection between the tympanic membrane and the oval window in the case of a missing ossicle was in 1901. Since then, numerous materials have been used to recreate the middle ear sound-conducting mechanism. Many materials have been used for ossicular substitution or reconstruction,

Attachment B

including both biologic and alloplastic materials. Biologic materials include autograft or homograft ossicles, cortical bone, teeth, and cartilage.

The most commonly used autograft material has been the incus body, which is often reshaped to fit between the manubrium of the malleus and the stapes capitulum. Autograft materials are not always available, or—as in patients with cholesteatoma—an ossicle may have microscopic squamous epithelium infiltration that precludes such use. Autografts have several disadvantages, including lack of availability in chronically diseased ears, prolonged operative time to obtain and shape the material, resorption and/or loss of rigidity (especially with cartilage), and possible fixation to the walls of the middle ear. Additionally, osteitis may exist within the ossicles, and the risk of residual cholesteatoma may be increased in patients with cholesteatoma.

Irradiated homograft ossicles and cartilage were first introduced in the 1960s in an attempt to overcome some of the disadvantages of autograft implants. Homograft ossicles or cartilage may be presculpted by the manufacturer, or they may be sculpted during surgery. Since 1986, homograft materials rarely are used because of the risk of disease transmission (eg, AIDS, Creutzfeldt-Jakob disease).

Because of the disadvantages of autograft materials and the potential risk of infection from homograft implants, alloplastic materials are the most commonly used materials for ossicular reconstruction today. Alloplastic materials can be classified as biocompatible, bioinert, or bioactive. In the late 1950s and the 1960s, biocompatible material, such as polyethylene tubing, Teflon, and Proplast, were used. Ossicular reconstruction with these materials often resulted in migration, extrusion, penetration into the inner ear, or significant middle ear reactivity. For these reasons, use of these solid polymeric substances was eventually abandoned.

In the late 1970s, a high-density polyethylene sponge (HDPS) that had nonreactive properties was developed. HDPS has sufficient porosity to encourage tissue ingrowth. The original form was a machined-tooled prosthesis (Plasti-Pore); a more versatile manufactured thermal-fused HDPS (Polycel) arrived later. This latter form permitted coupling with other materials, such as stainless steel, thus lending itself to a wide variety of prosthetic designs. A high incidence of extrusion occurs when either Plasti-Pore or Polycel is placed in contact with the tympanic membrane. Extrusion is reduced considerably when cartilage is placed between a Plasti-Pore or Polycel prosthesis and the tympanic membrane.

Silastic, stainless steel, titanium, and gold are other examples of biocompatible materials used for ossicular reconstruction.

Bioinert implants are materials that do not release detectable trace substances. The prototype bioinert material is dense aluminum oxide ceramic (Al2O3). This material was popular in Germany and Japan in the 1970s. The implant can be fit to the undersurface of the tympanic membrane without cartilage coverage.

Bioactive implants react favorably with the body's tissues to promote soft tissue attachment. The attachment is a direct chemical bond to the surface of the material, not merely a mechanical attachment that occurs with bioinert and biocompatible materials. Bioactive implants were introduced in the 1970s with the hope that this new material would have a lower incidence of extrusion than the porous polyethylene implants. The first of the bioactive implants were bioactive glasses (Bioglass and Ceravital). Bioactive glasses enjoy limited use today because of the difficulty in trimming the glass prostheses and their instability in infected environments.

Hydroxylapatite is another bioactive material. From a compatibility standpoint, hydroxylapatite is the most promising implant material currently in use. The most common form of hydroxylapatite for middle ear reconstruction is the dense form. The nonporous and homogenous nature of dense hydroxylapatite resists penetration by granulation tissue. This aspect can clearly be seen using scanning electron microscopy. Hydroxylapatite can be placed directly under the tympanic membrane without increased risk of extrusion.

The goal of this article is to review some of the more common materials and techniques for ossicular chain reconstruction currently in use. An exhaustive review of all materials and techniques is not feasible in a single article.

Problem: Ossiculoplasty is defined as the reconstruction of the ossicular chain. For purposes of

this discussion, reconstruction of the stapes (stapedectomy/stapedotomy) is not presented in this article.

The ideal prosthesis for ossicular reconstruction should be biocompatible, stable, safe, easily insertable, and capable of yielding optimal sound transmission. When the surgeon chooses a particular prosthesis, selection must be based on several factors, including compatibility and ease of configuring the prosthesis during surgery.

Conductive hearing loss from ossicular chain abnormalities may result from either discontinuity or fixation of the ossicular chain. In order of frequency, discontinuity most commonly occurs because of an eroded incudostapedial joint (occurring in approximately 80% of patients with ossicular discontinuity), an absent incus, or an absent incus and stapes superstructure. Ossicular fixation, exclusive of otosclerosis, most commonly occurs from malleus head ankylosis or from ossicular tympanosclerosis.

The problems associated with ossicular chain reconstruction in chronic otitis media are quite different from those in patients with a dry, infection-free middle ear. Some of the problems associated with chronic otitis media include tympanic membrane perforation, eustachian tube dysfunction, or cochlear deficits. These problems must also be considered to achieve optimal hearing.

Treatment of patients with cholesteatoma poses a unique set of problems. In order of importance, the goals of cholesteatoma removal are developing a safe ear, producing a clean dry ear, and improving or maintaining hearing. These goals sometimes are mutually exclusive. Specifically, a safe, dry ear may require removal of the posterior external auditory canal. Canal removal reduces middle ear volume, which may affect hearing.

Etiology: In more than 80% of patients, the cause of ossicular damage (ie, discontinuity, fixation) is cholesteatoma or chronic suppurative otitis media. Trauma or congenital malformations account for most of the remaining causes of ossicular damage.

Pathophysiology: The normal human middle ear couples sound from the low impedance sound energy in the ear canal through the tympanic membrane and ossicles to the relatively high impedance of fluid within the cochlea. Recent investigations of human middle ear mechanics indicate that traditional teaching of middle ear mechanisms should be modified. To provide a more comprehensive description, both traditional and recent discussions of the physiology of middle ear sound transmission are briefly discussed in this section.

Traditional teaching states that the acoustic transformer system of the middle ear is divided into 3 systems: the catenary lever (due to the tympanic membrane), the ossicular lever (due to ossicular action), and the hydraulic lever (due to the difference in area between the tympanic membrane and the stapes footplate).

Catenary lever

The attachment of the tympanic membrane at the annulus amplifies the energy at the malleus because of the elastic properties of the stretched drumhead fibers. Because the annular bone surrounding the tympanic membrane is immobile, sound energy is directed away from the edges of the drum and toward the center of the drum. The malleus receives the redirected sound energy from the edge of the drum because of the central location of the manubrium. The catenary lever provides at least a 2-fold gain in sound pressure at the malleus.

Ossicular lever

The ossicular lever is based on the concept that the malleus and incus act as a unit. The malleus and incus rotate around an axis running between the anterior mallear ligament and the incudal ligament. The ossicular lever is the length of the manubrium of the malleus divided by the length of the long process of the incus (approximately 1.3:1). Since the malleus and tympanic membrane act as coupled system, some authors believe that the ossicular lever value of 1.3:1 should be reduced to 1.15:1. The reduction can be supported because of the different areas of curvature of the drum and how this affects the lever ratio. Together, the ossicular and catenary levers provide a sound pressure advantage of 2.3:1, which is more than twice that of the ossicular lever acting alone.

Hydraulic lever

The hydraulic lever acts because of the size difference between the tympanic membrane and the stapes footplate. Sound pressure collected over the area of the tympanic membrane and transmitted to the area of the smaller footplate results in an increase in force proportional to the ratio of the areas (also known as the areal ratio). The average ratio has been calculated to be 20.8:1.

According to traditional teaching, the acoustic transformer theory predicts a middle ear gain of approximately 27-34 decibels (dB). This figure is derived as a product of the action of the catenary, ossicular, and hydraulic levers. Implied in the transformer analogy is the expectation that this gain is independent of frequency.

Recent investigations of the human middle ear indicate that the acoustic transformer theory should be modified. Merchant et al (1997) summarized the latest reports of human middle ear sound transmission. They proposed that middle ear sound transmission is the result of ossicular coupling, acoustic coupling, and stapes-cochlear input impedance. Middle ear aeration also is considered essential for proper middle ear sound conduction.

Ossicular coupling

Ossicular coupling refers to the sound pressure gain that occurs through the actions of the tympanic membrane and the ossicular chain. The pressure gain provided by the normal middle ear with ossicular coupling is frequency dependent. The mean middle ear gain is approximately 20 dB at 250-500 hertz (Hz), it reaches a maximum of about 25 dB around 1 kilohertz (kHz), and it then decreases at about 6 dB per octave at frequencies above 1 kHz.

The changes in gain above 1 kHz are caused by portions of the tympanic membrane moving differently than other portions, depending on the frequency of vibration. At low frequencies, the entire tympanic membrane moves in one phase. Above 1 kHz, the tympanic membrane divides into smaller vibrating portions that vibrate at different phases. Another factor for the change in gain above 1 kHz is slippage of the ossicular chain, especially at frequencies above 1-2 kHz. Slippage is due to the translational movement in the rotational axis of the ossicles or flexion in the ossicular joints. In addition, some energy is lost because of the forces needed to overcome the stiffness and mass of the tympanic membrane and ossicular chain.

Acoustic coupling

Acoustic coupling is the difference in sound pressures acting directly on the oval and round windows. Movement of the tympanic membrane produces a sound pressure in the middle ear that is transmitted to the oval and round windows. The pressure at each window is different because of the small distance between windows and the different orientation of each window relative to the tympanic membrane. In normal ears, the difference in pressures between the oval and round windows (acoustic coupling) is negligible.

In some diseased and reconstructed ears, the difference becomes significant and can greatly affect hearing. Specifically, when the ossicular chain is interrupted or absent, shielding of the round window results in redirection of all sound energy into the oval window, such as in Wullstein type IV tympanoplasty. When this is performed, acoustic coupling plays a significant role in sound pressure conduction for cochlear stimulation.

Stapes-cochlear input impedance

Stapes footplate motion is normally impeded by several anatomic structures, including the annular ligament, the cochlear fluids, the cochlear partition, and the round window membrane. Together, these structures result in stapes-cochlear input impedance. The round window impedance contribution is negligible in the normal ear. When the round window niche is filled with fluid or fibrous tissue, round window impedance increases, resulting in an increase in stapes-cochlear input impedance. Increases in this impedance cause conductive hearing loss.

Middle ear aeration

Ossicular coupling is impaired when the middle ear space (the air space of both the middle ear and the mastoid cavity) is reduced. The difference in sound pressures between the external

auditory canal and the middle ear facilitates tympanic membrane motion. In the normal ear, the middle ear air pressure is less than the pressure in the external canal. When the middle ear space is reduced (eg, by chronic ear disease or canal wall down surgery), the impedance and pressure of the middle ear increase relative to the external canal because the impedance of the middle ear space varies inversely with its volume. The pressure difference between the external canal and the middle ear leads to a subsequent reduction in tympanic membrane and ossicular motion. The minimal amount of air required to maintain ossicular coupling within 10 dB of normal has been estimated to be 0.5 mL.

Clinical: The clinical presentation of patients who would benefit from ossiculoplasty is quite variable. Conductive hearing loss may be the result of ossicular erosion or fixation from chronic ear disease, blunt or penetrating trauma, or congenital or neoplastic causes.

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The goal of ossicular chain reconstruction is better hearing, most typically for conversational speech. Ossiculoplasty is used to improve or to maintain the conductive portion of hearing loss. The aim of ossiculoplasty is not to close the air-bone gap per se but to improve the patient's overall hearing (ie, improve the air conduction score). A patient's perceived hearing improvement is best when the hearing level of the poorer-hearing ear is raised to a level close to that of the better-hearing ear. Small improvements in hearing are more likely to be appreciated by patients with bilateral hearing loss.

RELEVANT ANATOMY AND CONTRAINDICATIONS Section 4 of 11 [Back Top Next]

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Relevant Anatomy: A thorough knowledge of the anatomy of the tympanic membrane and the middle ear space is necessary prior to performing ossiculoplasty.

Contraindications: Relatively few contraindications to ossiculoplasty exist. Acute infection of the ear is the only true contraindication. Acute infection would most likely result in poor healing, prosthesis extrusion, or both. Relative contraindications include persistent middle ear mucosal disease, tympanic membrane perforation, and repeated unsuccessful use of the same or similar prostheses.

Imaging Studies:

- A thin-section CT scan of the temporal bones with axial and coronal views may provide the following information:
  - Extent of cholesteatoma or chronic ear disease (if present)
  - Size of the middle ear cavity
  - Presence, absence, and continuity of the ossicular chain
  - Presence of attic fixation of the malleus
  - Presence of otosclerosis
  - Bony structure of the inner ear
- The decision to perform a CT scan is based on the patient's history and physical examination findings. The final decision to perform a CT scan is at the discretion of the examining physician.

Diagnostic Procedures:

- Perform a thorough otoscopic examination, preferably with binocular microscopy.
- Inspect the preauricular skin and auricle. The presence of preauricular pits or tags or auricular deformities may suggest a congenital abnormality.
- Examine the external auditory canal for size, shape, and defects.
- Note the status of the tympanic membrane and, as much as possible, the middle ear.
- Perform pure tone audiometry with air/bone thresholds and masking, if necessary, prior to surgical planning.

Histologic Findings: Middle ear implants are unique in that one end must be coupled to the tympanic membrane and the other to bone or soft tissue. Ideally, the implant should not contact other tissue between the implant's 2 ends. The material also must maintain its shape, rigidity, and acoustic transmission properties. The outcome of middle ear implantation is determined largely by the status of the middle ear. Eustachian tube dysfunction can lead to early extrusion, and infection can lead to breakdown and resorption of an implant.

Ossicular reconstruction materials are divided into autografts, homografts, or alloplastic prosthetics. Each of these materials possesses unique properties when exposed to the environment of the middle ear. Similarly, unique problems are associated with each of these materials. Problems include graft failure, implant extrusion, and persistent or recurrent conductive hearing loss.

Autologous cartilage was one of the first materials used for ossicular chain reconstruction. In 1971, Smyth reported that cartilage struts removed at revision surgery showed erosion, suggesting the graft would not be stable over time (<3 y). Similar work by Merchant and Nadol in 1994 showed loss of rigidity on microscopic examination, chondromalacia on histologic examination, and resorption. The loss of stiffness is probably due to ingrowth of blood vessels with subsequent chondritis. These findings led the authors to conclude that cartilage struts are unsatisfactory as long-term implants.

Autologous incus grafts also have been used for some time. A strut or crutch in the short process of the incus is created for the malleus, with a cup made for the stapes capitulum. Autograft ossicular struts maintain their contour, shape, size, and physical integrity for at least 11 years (Merchant and Nadol, 1994). Ossicular grafts eventually may become nonvital because of loss of blood supply. Thermal injury during sculpturing may contribute to the loss of blood supply. Autologous ossicles subsequently undergo new bone formation and remodeling. The process is characterized by a slow creeping substitution of revascularized bone. The neo-osteogenesis is not vital for the transmission of sound.

Plasti-Pore, a HDPS, is an alloplastic material with a long clinical history. This material sets the standard by which the National Bureau of Standards tests other implant materials. HDPS has nonreactive properties and sufficient porosity to encourage tissue ingrowth.

Histologic examination of HDPS implanted for 1-4 years has shown extensive invasion of the porous spaces with fibrocytes, small round cells, and foreign-body giant cells. An envelope of fibrous tissue with a lining membrane of mucosal epithelium often forms around the implant. Some studies have demonstrated partial resorption of HDPS and replacement by fibrous tissue.

Clinical experience has shown the necessity of covering these HDPS alloplasts with cartilage to minimize the incidence of extrusion. Extrusion rates have averaged 3-5% in large series with 5-10 years of follow-up monitoring. Although most extrusions have occurred within the first year, some extrusions have occurred up to 5 years postoperatively.

Hydroxylapatite is currently one of the most common alloplastic materials used for ossicular reconstruction. Hydroxylapatite is a polycrystalline calcium phosphate ceramic that has the same chemical composition as bone. This material chemically attaches to bone and is osteoconductive. It forms a direct bond with bone at the hydroxylapatite/tissue interface. This bond is associated with an electron-dense layer at the interface composed, at least in part, of calcium phosphate in the form of hydroxylapatite. This epitaxy or continuity between the artificial and biologic hydroxylapatite crystals might explain the bonding osteogenesis at the interface. If placed next to the scutum, osseointegration can occur, with subsequent conductive hearing loss. Cartilage is not required when using hydroxylapatite.

Within the first 2 weeks of implantation, a large proportion of hydroxylapatite implants are covered with an epithelial layer. With time, the implant gradually becomes completely covered by this epithelial layer. The final epithelial layer contains all cell types characteristic for the middle ear. An epithelial covering resembling that in the normal middle ear indicates good biocompatibility of an implant material.

Hydroxylapatite is produced in both porous (pore size >100 μm) and dense (pore size <30 μm) forms. The dense form is the type used in ossicular prosthetics. The size of the macropore has a direct influence on the kind of tissue that grows into these pores. Generally, a pore size larger than 100 μm favors the ingrowth of bone, whereas a pore size of 30 μm allows fibrous tissue ingrowth. With the porous implant materials, a firmer fixation and a smaller fibrous capsule occur compared to the dense form.

Titanium is another common alloplastic material. Studies in rabbits have shown that within 28 days after implantation, a thin, noninflamed, even layer of epithelium forms over the inserted implant. Similar results in human studies have shown the same type of reactivity. Titanium forms a biostable titanium oxide layer when combined with oxygen. Titanium has shown significant biostability in the middle ear for the past decade.

The properties of titanium make it possible to manufacture an extremely fine and light prosthesis with substantial rigidity in the shaft. Furthermore, differential processing of the material surfaces triggers various tissue reactions. For example, if titanium implants are rough milled, their contact points are increased. Rough-milled surfaces are most appropriate in areas that contact cartilage or the stapes head or footplate. Conversely, the smoother the surface, the less connective tissue reaction occurs, and the epithelial covering is minimized.

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Medical therapy: Hearing amplification is an alternative to ossiculoplasty in patients with conductive or mixed hearing loss.

Surgical therapy: The status of the ossicular remnants determines which implant can be used. In general, better hearing results are achieved when as much of the remaining functional ossicular chain as possible is used during reconstruction.

The weight of a prosthesis has an effect on sound conduction in the middle ear; this has been proven with standardized measurements. A weight of more than 5 mg can affect sound transmission above 1 kHz; thus, it is better to use a prosthesis that weighs less than 5 mg.

Preoperative details: See Workup.

Intraoperative details: Alloplastic materials are the most commonly used materials for ossicular reconstruction.

Palpate whatever ossicles are present to ensure their mobility. If the malleus head is fixed, remove it to achieve a mobile malleus handle and to prevent refixation. To remove the malleus head, first remove the incus; then, section the neck of the malleus. If the stapes footplate is fixed, a stapedectomy or stapedotomy can be performed. Open the footplate only

when there is an intact tympanic membrane and no evidence of active or chronic infection.

The authors recommend removal of the remaining incus and/or malleus head when cholesteatoma is in continuity with these ossicles. In this way, the risk of residual cholesteatoma is reduced because the cholesteatoma may infiltrate the bone of the ossicles. The incus body also may have scar tissue blocking the antrum.

Erosion of incudostapedial joint

Erosion of the incudostapedial joint with an intact, mobile malleus is the most common ossicular defect in children and adults. Reconstruction of this type of defect may be accomplished by several means. The first is to reconstruct the joint itself. One of the most common prostheses for joint replacement is the Applebaum incudostapedial joint prosthesis (Gyrus ENT, Bartlett, Tenn), which is made from hydroxylapatite.

This prosthesis is an elongated cube with a trough on one face to receive the residual incus long process and a hole on the opposite face for the stapes neck and capitulum (see Image 1). Placement is accomplished by centering the hole of the prosthesis on the stapes capitulum while lifting the long process of the incus into the trough. If the incus defect is too small to allow easy insertion of the prosthesis, use a malleus nipper or laser to slightly trim the long process of the incus. Palpate the malleus to verify good motion transmission through the prosthesis to the stapes. Supporting packing material is not necessary because the prosthesis snaps firmly into position. The Applebaum prosthesis comes in various sizes, is easy to use, and has a low extrusion rate. With time, the prosthesis may slip off the incus if the incus long process continues to erode.

Another option for joint replacement is a Kurz angular prosthesis (Plester) (Kurz Medical, Inc, Norcross, Ga) made of a gold shaft, gold cup, and titanium clips (see Image 2). The gold cup is placed initially on the head of the stapes. Next, the clips are crimped to the long process of the incus. One advantage of the device is that the shaft comes in various lengths to accommodate different size remnants of the long process of the incus.

A different means to reconstruct the incudostapedial joint is to bypass the stapes superstructure. This may be accomplished with a specially designed prosthesis, the Lippy-modified Robinson stainless steel prosthesis. Initially, the shaft of the prosthesis is placed on the stapes footplate between the crura, thus bypassing the stapes capitulum. The open side of the specially designed well is guided to the long process, which is lifted to enter the well under slight tension.

Supporting packing material is not necessary because the prosthesis fits snugly between the crura, which hold the prosthesis in place. If the remaining long process is too short, the tip will be too large to fit into the well of the prosthesis, and an incus replacement technique should be used (see Malleus present, stapes present). The hearing results are similar when comparing the results of either reconstruction of the incudostapedial joint with a joint prostheses or reconstruction performed through bypass of the stapes superstructure.

Polymaleinate ionomer cement (Oto-Cem, Oto-Tech, Raleigh, NC) has recently been used to bridge gaps to recreate the incudostapedial joint (Feghali, 1998). Preliminary results with this technique seem promising.

Some authors advocate bypassing the incus remnant altogether by performing an incus replacement technique (see Malleus present, stapes present).

Malleus present, stapes present (M+S+)

In this instance, 3 options exist for reconstruction. The first option is reconstruction using an incus replacement prosthesis. A second option for reconstruction when the incus is absent and the malleus and stapes are present is to bypass the malleus. This may be accomplished using a partial ossicular reconstruction prosthesis (PORP). A third option is reconstruction using a total ossicular reconstruction prosthesis. The base of the total ossicular reconstruction prosthesis is placed on the footplate between the fallopian canal and the stapes superstructure. In theory, placement of the prosthesis in this manner may help with cradling, centering, and stabilizing the prosthesis (Moretz, 1998; Murugasu, 2005).

Reconstruction using a PORP is discussed in the Malleus and incus absent, stapes present section. Perform reconstruction with an incus replacement prosthesis only when the angle between the long axis of the stapes capitulum and malleus handle is less than 45° (preferably <30°). Angles more than 45° prevent proper sound transfer between the stapes and malleus. Specifically, some sound energy is converted into an inefficient rocking motion at the footplate if the manubrium is too far anterior to the stapes.

Possible options for incus replacement prostheses include the Applebaum incus replacement prosthesis, the Wehrs single- or double-notched incus prosthesis (Image 3), or the short Black Spanner Strut (Image 4). All products are from Gyrus ENT, Bartlett, Tenn. Each of these prostheses is made of hydroxylapatite except for the base of the Wehrs prosthesis, which is made of HAPEX, and the shaft of the Black Spanner Strut, which is made of fluoroplastic. HAPEX is

a composite material made of 40% hydroxylapatite and 60% polyethylene by volume. By weight, HAPEX is more than 70% hydroxylapatite. Unlike hydroxylapatite, which is brittle and difficult to trim, HAPEX and fluoroplastic are trimmed easily with a scalpel.

Insertion of the Applebaum incus replacement prosthesis is performed by placing the appropriate size prosthesis on the promontory. With one hand, the malleus is elevated using a right-angle pick. With a right-angle pick in the other hand, the prosthesis is grasped under the groove that will engage the stapes. The prosthesis is brought up under the manubrium while the groove in the base of the prosthesis is lifted over the head of the stapes. Bring the prosthesis to a vertical and stable position halfway between the tip of the manubrium and the tensor tympani muscle. Moving the prosthesis closer to the tip can tighten the fit. As with all incus replacement prostheses, supporting packing material is not necessary because the prostheses snap firmly into position.

The Wehrs prosthesis insertion technique is similar to that for the Applebaum incus prosthesis. If necessary, the base of the Wehrs prosthesis can be trimmed with a scalpel. To improve the stability of the prosthesis, a notch to accommodate the stapes tendon may be fashioned in the inferior portion of the HAPEX shaft.

Placement of the short Black Spanner Strut is accomplished by trimming the fluoroplastic shaft to size, based on the distance and angle from the malleus to stapes. The hydroxylapatite head then is reattached to the trimmed shaft. The crural notches on the base of the shaft are aligned on the stapes, the malleus is lifted with a pick, and the head of the prosthesis is engaged on the mid portion of the manubrium.

When using any of the above-mentioned prostheses for incus replacement, the tensor tympani tendon may be stretched or sectioned to increase the mobility of the malleus and to improve the ease of placement of the prosthesis. If the head of the malleus has been removed to maintain the stability of the manubrium, it is often better to stretch rather than cut the tensor tendon.

Malleus present, stapes footplate present (M+S+)

When the malleus is present and only the stapes footplate remains, 2 possible options are available for reconstruction. The first option is to use an incus-stapes prosthesis. The second option is to bypass the malleus and to use a total ossicular reconstruction prosthesis (TORP). Reconstruction using a TORP prosthesis is discussed in the Malleus and incus absent, footplate present section. Several incus-stapes prostheses are available. Two of the most common include the Goldenberg and the Wehrs HAPEX (Image 5) implants (each from Gyrus ENT, Bartlett, Tenn).

For proper placement, the HAPEX shaft of the implants is trimmed after measuring the distance from footplate to the mid portion of the malleus. (Measurement can be performed using any of several commercially available measuring rods.) Then, the shaft is centered on the stapes footplate. While lifting the manubrium, the prosthesis is brought into place under the mid portion of the manubrium. As with the incus replacement prostheses, tension can be increased by moving the prosthesis toward the tip of the manubrium. The middle ear may be packed with gelatin foam for further support. Take care to avoid too much tension on the footplate, which could displace the shaft into the vestibule. The usual length of the incus-stapes prosthesis is 4-6 mm.

Malleus and incus absent, stapes present (M-S+)

A PORP is the best option for ossicular reconstruction when the malleus and incus are absent in the presence of an intact stapes. Numerous PORPs are available. Examples include the Goldenberg HAPEX (Gyrus ENT, Bartlett, Tenn) (see Image 6) and the Kurz titanium PORPs (Kurz Medical, Inc, Norcross, Ga) (see Image 7).

As with many PORPs, the Goldenberg HAPEX PORP has a rounded hydroxylapatite head and a trimmable shaft. The Goldenberg HAPEX PORP has a malleable connection between the shaft and head that tilts to conform to the orientation of the tympanic membrane. The hydroxylapatite head can be placed directly under the tympanic membrane without the use of a cartilage cover. Initially, the distance from the estimated final resting position of the tympanic membrane (or graft) to the head of the stapes is measured. The shaft of the PORP should be trimmed slightly longer than this measurement. In this way, the prosthesis will "tent" the tympanic membrane (or graft) and help prevent dislocation of the prosthesis. A small notch for the stapedial tendon may be made at the base of the trimmed shaft to provide further stability.

The cannulated shaft is placed over the head of the stapes and the prosthesis is supported with gelatin foam on all sides. The tympanic membrane (or graft) then is draped over the head of the prosthesis. To prevent osseointegration with the canal wall, isolate the prosthesis from the bony external auditory canal with gelatin foam. When using gelatin foam, allowances must be made for its expansion when moist. Expansion of the foam can lift the prosthesis from the stapes, thus causing conductive hearing loss.

The proper length of the prosthesis is important to prevent extrusion. If the prosthesis is too long, the prosthesis can elevate the tympanic membrane too far laterally. Significant elevation of the drum may result in pressure necrosis of the

tympanic membrane with extrusion of the prosthesis. On the other hand, if the prosthesis is too short, conductive hearing loss occurs. If the surgeon is new to the use of PORPs, the authors recommend trimming the shaft slightly longer on the first cut, rather than risking making the shaft too short. The exact placement and length then can be determined by trial and error. The usual length for a PORP prosthesis is 2.0-4.5 mm in canal wall up cases and approximately 1 mm in canal wall down cases.

The Kurz Dusseldorf-type BELL PORP is made entirely of titanium. The Kurz PORP comes in various lengths. The flat head of the prosthesis is a grid that allows visualization of the stapes through the grid holes during placement. A cup with 4 malleable bands attaches to the bottom of the shaft. The opening between the bands is designed to accommodate the stapedial tendon. If desired, the bands may be crimped over the stapes capitulum for a more secure fit. A cartilage covering over the head of the prosthesis is necessary to prevent extrusion. A cartilage thickness of 500 μm is considered a good compromise between sufficient mechanical stability and low acoustic transfer loss (Zahnert, 2000).

Kurz has designed a special cartilage cutter to achieve a thickness of 500 μm. As with the Goldenberg HAPEX PORP, gelatin foam is necessary to support the prosthesis. Carefully stabilize the cartilage with one instrument while draping the tympanic membrane (or graft) over the cartilage/prosthesis with another instrument. If not stabilized, the cartilage shifts the prosthesis off the stapes.

Malleus and incus absent, footplate present (M-S-)

In this situation, a TORP is the best option for reconstruction. As with PORPs, numerous TORPs are available. The difference between the Goldenberg HAPEX PORP and TORP is that the TORP has a longer, narrower HAPEX shaft. As with the PORP, the Goldenberg HAPEX TORP also has a malleable connection between the shaft and head that tilts to conform to the orientation of the tympanic membrane. The steps for placement of the TORP are the same as that for PORP placement. The only difference in placement is that some surgeons recommend placement of a footplate shoe. The shoe helps to ensure contact and stability with the stapes footplate.

One such shoe is the Goldenberg hydroxylapatite footplate shoe (see Image 8). The shoe press-fits on the end of the Goldenberg implant shaft and adds an extra 0.5 mm to the implant length. The footplate shoe is designed to fit between the crura remnants on the footplate. The shoe can be placed onto a tissue graft in the oval window or onto the stapes footplate. The shoe can be used with any implant that has an 0.8-mm diameter. The usual length for the TORP prosthesis is 4-7 mm in the case of canal wall up cases and approximately 3 mm in canal wall down procedures.

The Kurz Dusseldorf-type titanium AERIAL TORP (Kurz Medical, Inc, Norcross, Ga) base consists of a piston that rests on the footplate (see Image 9). Otherwise, the head is the same as that for the PORP. Placement of the Kurz TORP also requires the use of a cartilage cover.

Postoperative details: Ask patients to avoid nose blowing, to sneeze with an open mouth, and to avoid lifting heavy objects for the first 2 weeks after surgery. In complying, the patient prevents significant pressure changes in the middle ear that could compromise the result of surgery. Water should be kept out of the ear until the external auditory canal and tympanic membrane are healed.

Follow-up care: Ideally, provide follow-up care to patients for a minimum of 3 years (10 y in patients with cholesteatoma). Prosthesis extrusions are most common 1-3 years after ossiculoplasty. After 3 years, the extrusion rate is not significant.

COMPLICATIONS Section 7 of 11 [Back Top Next]

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The risks of ossiculoplasty include sensorineural hearing loss, ipsilateral taste disturbance, dizziness, tympanic membrane perforation, infection, tinnitus and, rarely, facial nerve paralysis.

No hearing improvement after surgery is a functional complication. If this occurs, the authors suggest waiting at least 6 months before attempting revision ossiculoplasty. If a tympanic graft has been placed, delay revision ossiculoplasty because the graft must be allowed to thin. In addition, middle ear pressure may change, depending on the status of eustachian tube function. If necessary, revision is easier at 6 months because the tympanic membrane or graft is thin and because decreased vascularity is present in the middle ear.

OUTCOME AND PROGNOSIS Section 8 of 11 [Back Top Next]

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The status of the tympanic membrane and middle ear has a significant influence on the prognosis of hearing outcomes in ossiculoplasty. For this reason, Kartush developed the Middle Ear Risk (MER) Index (see Table 1). The MER index is a means to improve the accuracy of reporting of ossiculoplasty results and a means to allow meaningful comparisons among studies. Table 2 provides examples of MER index determinations.

Table 1. Middle Ear Risk Index

Risk Factor	Risk Value
Otorrhea (Belucci)	
I. Dry	0
II. Occasionally wet	1
III. Persistently wet	2
IV. Wet, cleft palate	3
Perforation	
Absent	0
Present	1
Cholesteatoma	
Absent	0
Present	1
Ossicular status (Austin/Kartush)	
O: M+I+S+ (intact ossicular chain)	0
A: M+S+ (malleus present, stapes present)	1
B: M+S- (malleus present, stapes absent)	2
C: M-S+ (malleus absent, stapes present)	3
D: M-S- (malleus absent, stapes absent)	4
E: Ossicle head fixation	2
F: Stapes fixation	3
Middle ear - Granulations or effusion	
No	0
Yes	1
Previous surgery	
None	0
Staged	1

Revision	2

Table 2. Middle Ear Risk Index Determinations

Prognosis/Risk	MER Index
Best prognosis (normal ear)	0
Mild risk	2
Moderate risk	5
Severe risk	7
Worst prognosis (end stage)	12

Hearing results typically are classified based on the postoperative air-bone gap. Classifications based on the air-bone gap are usually stratified as excellent (<10 dB), good (11-20 dB), and fair (21-30 dB). Initial hearing results may diminish with time; therefore, results should be reported at 1, 3, and 5 years.

Prosthesis extrusion has varied from 5-39% in the literature. The rate of extrusion depends on several factors, the most important of which is the status of the middle ear and eustachian tube and the implant material.

The following is a list of situations that generally have a more favorable prognosis for improved hearing compared to their anatomic counterpart:

- Malleus handle present versus handle absent
- Intact stapes arch versus absent arch
- Canal wall up versus canal wall down
- Mastoidectomy not necessary versus mastoidectomy performed

In addition, hearing results generally worsen as the number of revisions increases. The worst results typically occur in patients with congenital ossicular abnormalities.

In general, the better the air conduction and the smaller the preoperative air-bone gap, the greater the chance for a successful hearing result. Goldenberg suggests that this may be because patients with these characteristics have better eustachian tube function, healthier mucosa, and less ossicular damage compared to patients with a poor preoperative air-bone gap (Goldenberg, 2000).

FUTURE AND CONTROVERSIES

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Aeration of a mucosal-lined tympanic cavity is essential for a functioning middle ear. Extrusions of even the best-designed prostheses occur because of abnormal middle ear pathology such as atelectasis, middle ear fibrosis, recurrent cholesteatoma, tympanic membrane perforation, and otitis media.

Various polymers have been developed in an attempt to maximize prosthetic biocompatibility and ease of use, while minimizing the chance of extrusion.

In addition to biocompatibility, cost containment issues have influenced the development of ossicular prostheses. One of the greatest challenges in the future will be to define the appropriate prosthetic design for optimal sound transmission. Consideration of the prosthesis weight, head size, and footplate attachment are future research questions that must be addressed in a scientific biologic model.

Some of the controversial issues of ossiculoplasty include whether revision surgery should be advised and deciding when a hearing aid is a better option for hearing improvement. These controversies have continued for some time and

will continue until implant and hearing aid technology are improved and well-controlled studies are performed.

In terms of surgical technique, each surgeon should choose the technique and prosthesis that provides the best result for his or her patients.

PICTURES **Section 10 of 11** [Back Top Next]

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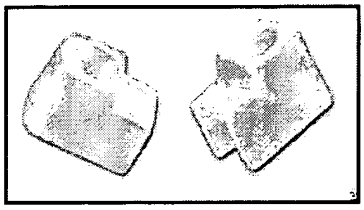
Caption: Picture 1. Applebaum incudostapedial joint prosthesis.



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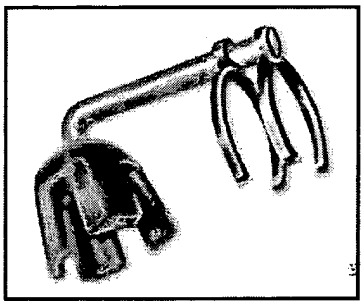
Picture Type: Image

Caption: Picture 2. Titanium incudostapedial joint prosthesis.



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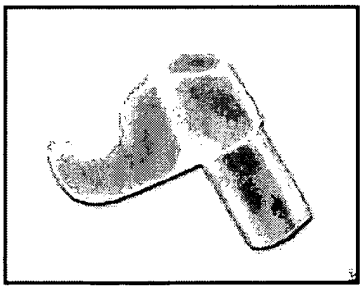
Picture Type: Image

Caption: Picture 3. Wehrs single-notched incus replacement prosthesis.



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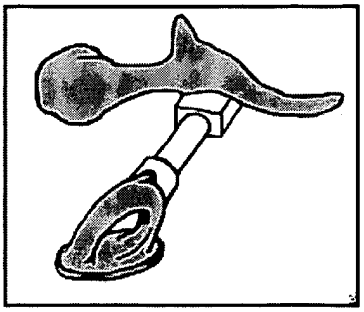
Picture Type: Image

Caption: Picture 4. Black Spanner Strut.



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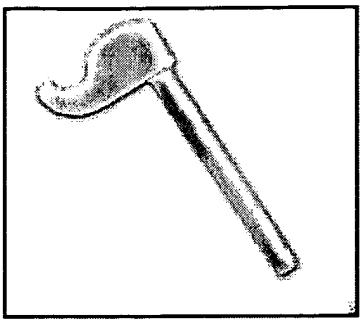
Picture Type: Image

Caption: Picture 5. Wehrs HAPEX incus-stapes prosthesis.



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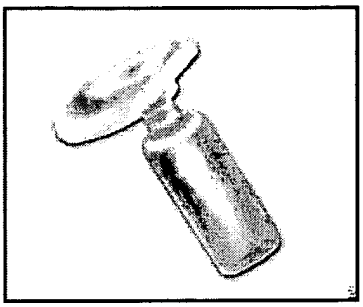
Picture Type: Image

Caption: Picture 6. Goldenberg HAPEX partial ossicular reconstruction prosthesis.



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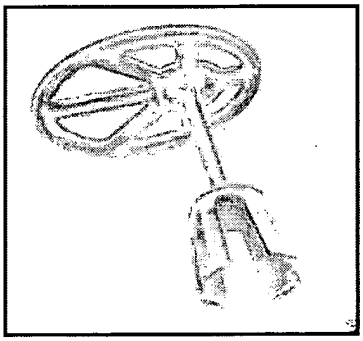
Caption: Picture 7. Dusseldorf-type BELL partial ossicular reconstruction prosthesis.



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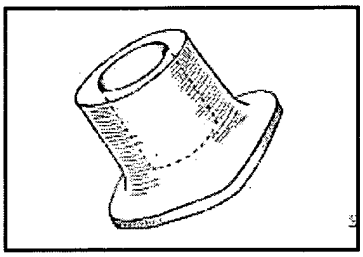
Picture Type: Image

Caption: Picture 8. Goldenberg hydroxylapatite footplate shoe.



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Picture Type: Image

Caption: Picture 9. Dusseldorf-type titanium AERIAL total ossicular reconstruction prosthesis.

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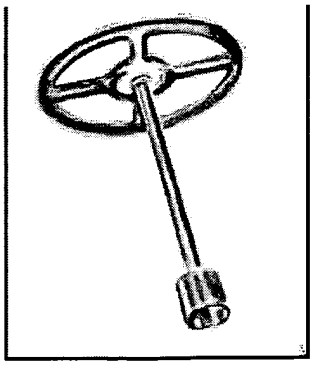

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Middle Ear, Ossiculoplasty excerpt

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1: Kidney Int. 2003 Feb;63(2):702-8.

Tissue adhesion to bioactive glass-coated silicone tubing in a rat model of peritoneal dialysis catheters and catheter tunnels.

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BACKGROUND: Silicone peritoneal dialysis catheters do not develop tissue ingrowth, lack a mechanical barrier to periluminal bacterial migration and need cuffs for anchorage. We hypothesized that a bioactive glass coating composed of silicon, calcium, sodium and phosphorous oxides would cause a beneficial tissue reaction causing catheter adhesion, and tested this in a rat model. METHODS: A hexane solvent-based method of coating silicone tubes with Bioglass powder was used, which maintained flexibility, and then the ultrastructure was confirmed with scanning electron microscopy (EM). Segments 2.5 cm were implanted subcutaneously in 8 Sprague-Dawley rats, with uncoated tubes as a contralateral control, and histology was done at 2, 4 and 6 weeks, including special stains and EM. RESULTS: The uncoated segments grossly had no adherence to surrounding tissue, and were physically separate from a thin fibrous capsule of approximately 50 micro width. Trichrome stains demonstrated the capsule was rich in collagen. There was minimal adjacent tissue reaction. In contrast, the coated tubes were palpably fixed to the soft tissues, and sections demonstrated an adjacent prominent layer of macrophages and multinucleated giant cells. Small numbers of lymphocytes were noted. This cellular reaction increased over the 6-week implant duration, and was also associated with neovascularization of the tissue adjacent to the segments (33 vessels in coated vs. 20 in controls per x 200 field, $P < 0.0001$). Many refractile silicone particles and prominent multinucleated giant cells were present, with small numbers of lymphocytes and macrophages. Stains showed scattered discontinuous calcific deposits. These findings are consistent with reports that the Bioglass(R) silicon oxide leads to the formation of a layer of hydroxyapatite, which binds to collagen and induces a tissue cellular

Attachment C

reaction. CONCLUSIONS: In summary, bioactive glass coatings can improve the tissue retention of silicone tubing by promoting adhesion by collagen and cell proliferation, and are promising for future studies of peritoneal dialysis catheters.

PMID: 12631137 [PubMed - indexed for MEDLINE]